Introduction

The CDC expanded HIV screening guidelines in 2006 to include routine testing of all individuals between the ages of 13-64 in all healthcare settings. This widespread screening approach may be facilitated by the recent FDA approval of two automated anti-HIV-1/2 serologic diagnostic assays. The aim of this study was to evaluate one of these two assays, the Bio-Rad Centaur® HIV 1/2 Enhanced (EHIV) assay (Siemens Diagnostics, Tarrytown, NY) (ADVIA). We performed a retrospective comparison study with our current manual method, Bio-Rad GS HIV-1/2 Plus O EIA (Bio-Rad Laboratories, Redmond, WA) (GS) using Western blot result as confirmation of HIV infection.

Results

Figure 1: Assay comparison algorithm. The A) WB results and B) GS EIA results for 96 samples were obtained from the Bio-Rad systems as described in Materials and Methods. The WB results were confirmed by ADVIA in duplicate. The (C) Advia assay results were obtained to complete the data set. The results were interpreted according to the package insert. The arrow indicates a signal cut-off value that was used to distinguish positive from negative samples.

Materials and Methods

Sixty-nine (69) patient samples that had Western blot (WB) confirmation results available were tested using both the GS and the ADVIA assays according to the package inserts. The samples consisted of 28 positive, 34 negative, and 34 indeterminate WB results. Because WB patterns that did not meet the criteria [1] were not reactive by GS and ADVIA, and 7 were repeatedly reactive by GS and negative by ADVIA, 3 were non-reactive by GS and reactive by ADVIA, and 7 were repeatedly reactive by GS and reactive by ADVIA. For the 16 “indeterminate 1” samples, 10 were negative by GS and ADVIA, and 6 were repeatedly reactive by GS and negative by ADVIA. For the 16 “indeterminate 2” samples, 7 were repeatedly reactive by GS and positive by ADVIA, 7 were reactive by GS and reactive by ADVIA, 1 was reactive by GS and negative by ADVIA, and 1 was reactive by ADVIA but negative by GS. The ADVIA assay detected infection 3 days and 2 days earlier than GS for PRB941 and PRB944, respectively.

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Materials and Methods

Samples with representative Western blot (WB) (GS HIV-1 Western Blot, Bio-Rad Laboratories, Redmond, WA) results and then corresponding EIA results (Bio-Rad GS HIV-1/2 Plus O EIA, Bio-Rad Laboratories, Redmond, WA) were obtained by querying the ARUP database. Since the purpose of this study was to compare the sensitivity and specificity of the WB assays, we purposely biased the sample set toward “indeterminate” WBs or negative WBs with an initial positive EIA. The samples and results were de-identified for compliance with the HIPAA.

Western blot results were interpreted according to the package insert and CDC criteria. We internally further subcategorized “indeterminate” WB results into “indeterminate 1” for samples with only non-cardinal bands and as “indeterminate 2” for samples with one cardinal band of any intensity.

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Summary

Both the GS and ADVIA HIV assays demonstrated 100% sensitivity, when using the WB confirmation result as the gold standard. Negative agreement or specificity was lower because expected for both assays tested, when using a positive WB for specificity, because the study was heavily biased towards samples with indeterminate Western blot results.

Using our stratification approach for indeterminate WB results, the ADVIA assay appears to have improved specificity compared to the GS assay, as it would have eliminated 6 WB samples that are not likely to be infected.

Indeterminate samples with at least one cardinal band were less likely to be reactive with ADVIA than GS.

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